

BACITRACIN ZINC AND POLYMYXIN B SULFATE - bacitracin zinc and polymyxin b sulfate ointment

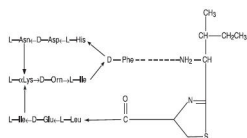
Akorn, Inc.

Rx only

DESCRIPTION

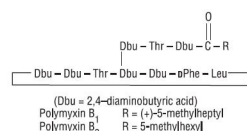
Bacitracin Zinc and Polymyxin B Sulfate Ophthalmic Ointment is a sterile antimicrobial ointment for ophthalmic use.

Bacitracin zinc is the zinc salt of bacitracin, a mixture of related cyclic polypeptides (mainly bacitracin A) produced by the growth of an organism of the licheniformis group of *Bacillus subtilis* var Tracy. It has a potency of not less than 40 bacitracin units per mg. The structural formula for bacitracin A is:



bacitracin A

Polymyxin B Sulfate is the sulfate salt of polymyxin B₁ and B₂ which are produced by the growth of *Bacillus polymyxa* (Prazmowski) Migula (Fam. Bacillaceae). It has a potency of not less than 6,000 polymyxin B units per mg, calculated on an anhydrous basis. The structural formulae are:



Each gram contains: Bacitracin zinc equal to 500 bacitracin units and polymyxin B sulfate equal to 10,000 polymyxin B units, white petrolatum and mineral oil.

CLINICAL PHARMACOLOGY

Polymyxin B attacks gram-negative bacilli, including virtually all strains of *Pseudomonas aeruginosa* and *H influenzae* species. Bacitracin is active against most gram-positive bacilli and cocci including hemolytic streptococci.

INDICATIONS AND USAGE

For the treatment of superficial ocular infections involving the conjunctiva and/or cornea caused by organisms susceptible to bacitracin zinc and polymyxin B sulfate.

CONTRAINDICATIONS

This product is contraindicated in those individuals who have shown hypersensitivity to any of its components.

WARNINGS

Ophthalmic ointments may retard corneal healing.

PRECAUTIONS

As with other antibiotic preparations, prolonged use may result in overgrowth of nonsusceptible organisms, including fungi. Appropriate measures should be taken if this occurs.

DOSAGE AND ADMINISTRATION

Apply the ointment every 3 or 4 hours for 7 to 10 days, depending on the severity of the infection.

HOW SUPPLIED

Bacitracin Zinc and Polymyxin B Sulfate ophthalmic ointment USP, sterile, each gram contains bacitracin zinc equal to 500 bacitracin units and polymyxin B sulfate equal to 10,000 polymyxin B units, in a tube of 3.5 g (1/8 oz) with ophthalmic tip.

NDC 17478-238-35

STORAGE

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Manufactured By: Akorn, Inc.

Lake Forest, IL 60045

AKP00N

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